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BY ELECTRONIC MAIL

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Re: Comments of the American Chemistry Council on DTSC Draft Stage 1 Alternatives Analysis Guide

The American Chemistry Council (ACC)[1] is pleased to submit these comments on the Department of Toxic Substances Control's (DTSC) Safer Consumer Products (SCP) Draft Stage 1 Alternatives Analysis Guide. ACC has been an active stakeholder in the development and implementation of California's Safer Consumer Products Regulation, and we view the development of this Guide as an important opportunity for DTSC to offer meaningful, actionable, concise, and clear guidance with respect to how the agency will apply the Regulation to a Stage 1 Alternatives Analysis (AA).

We appreciate DTSC's efforts to maintain flexibility for Responsible Entities conducting Alternatives Analyses. That said, for the program to be effective, it is important that Responsible Entities have certainty as to when their AAs, which will be the culmination of significant effort and expenditure, will be deemed compliant with the regulations and accepted by DTSC. For the program to work, it is imperative that where it is immediately apparent that there is no suitable, commercially available chemical replacement, the program can move quickly and efficiently to assess regulatory responses such as engineering and administrative controls. It is thus important that Responsible Entities have the opportunity to offer, and have considered, cost and performance data in Stage 1.

We note that our comments on Stage 1 are contingent on DTSC's handling and release of its "Stage 2" Guide. The "Stage 1" and "Stage 2" guidance must be read together to be able to offer informed comment on the entire AA process.

Our general comments and specific comments are set out below.

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[1] *The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is an $812 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for twelve percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.*

General Comments

I. The Guide Should be Revised to Provide Clearer, More Actionable Guidance.

Section 69505 of the SCP regulations requires DTSC to make available guidance materials to "assist" persons in performing AAs. For guidance to provide meaningful assistance it should avoid replicating the regulations. Instead, it should serve to answer key questions, provide examples, include references to resources and tools, and offer illustrative flowcharts to demonstrate sequences and timelines. We appreciate that DTSC intends to offer significant flexibility to Responsible Entities in the development of AAs. But it is counterproductive if regulatory flexibility is administered in a manner that leaves Responsible Entities uncertain as to how and when they will achieve agency approval of a Stage 1 AA. In short, Responsible Entities need better, more definitive guidance so they can successfully navigate the Stage 1 AA step and obtain agency approval before moving to Stage 2.

Section 69505 of the regulations sets forth detailed rules regarding steps in the AA process, timing, and content categories. They leave unanswered, however, many questions that the Guide can and should address. We suggest that the DTSC include a detailed decision tree to better assist Responsible Entities to focus on factors that are relevant to the Priority Product and that rely on science based, credible information without implying that "all" data and information must be part of an AA.

Since DTSC has now posted examples of AAs on its website, we suggest that these be cross-referenced in the Guide and a live weblink offered. Additionally, DTSC should indicate if these examples meet the Stage 1 guidance or not, with accompanying explanation.

II. The Guide Should Include Comprehensive References to Tools Suitable for Use in the AA Process and Note Key Limitations.

A variety of tools are publicly available for use in conducting AAs. These include hazard and exposure screening tools, life cycle tools, and decision science tools and algorithms. While the Guide offers some examples of available tools, we suggest that DTSC seek to provide a more comprehensive list of available tools in the Guide itself.[2] For that matter, many tools are suitable for limited purposes or screening purposes only, and some commentators have observed that the outputs of hazard screening tools can vary wildly, a discrepancy that becomes more significant with different sources of input data.

DTSC could also explain key restrictions or limitations on the use of particular tools as part of its commentary. For example, DTSC could explain the difference and limits of scoping, screening, and simplified Life Cycle Assessment tools following ISO 14040 and 14044 guidelines. Another example is the use of the hazard screening tool GreenScreen. Panelists at the November 12-13 Green Ribbon Science Panel noted that GreenScreen is incomplete for SCP purposes because it "doesn't cover everything in the regulations." GreenScreen is also acknowledged to have other limitations. GreenScreen does not incorporate the concept of tiered testing, but rather advocates for "full information from chemical suppliers." The "greenest" rating, Benchmark 4, requires that there be data for all 18 endpoints including higher tier endpoints of carcinogenicity, reproductive, developmental, neurodevelopmental, neuro- and chronic aquatic toxicity. This is inconsistent with standard practices in toxicology that emphasize an integrated testing framework based on tiered testing and endpoint-specific decision triggers to identify targeted higher tier testing. Further, there is little consideration of use and exposure in

[2] For example, for lifeycle tools, we have identified the availability (without commentary with respect to use or limitations) of Aveny LCA 2; BEES; BIRDS; eBalance; Ecodesk; GaBi; Global Water Tool; Greenscope; TRACI; openLCA; Quantis Suite 2.0; SHEDS; SimaPro; GaBi; Sustainable Minds; Umberto NXT Universal; and Water Risk.

GreenScreen, which is also relevant to scientifically-based decisions about the need for higher tier testing, indicating which specific endpoints and tests warrant further evaluation, and which do not. We believe that these additions and additional explanation would help DTSC meet its statutory obligation to ensure that the tools available are in a form that allows for ease of use and transparency of application.

III. The Guide Should Clarify that the Scope of an AA Should be Consistent with Statutory Authority.

The Safer Consumer Products law applies to covered consumer products, including their chemical constituents and ingredients. Authorized regulatory responses that DTSC may ultimately take are set out in Section 25253(b), and focus on the presence or use of a chemical of concern in a consumer product. While Section 25253(b)(2) allows DTSC to promulgate regulations that may "impose requirements" to "provide additional information needed to assess a chemical of concern and its potential alternatives," this statutory authority is not boundless. A consumer product manufacturer, for example, cannot be compelled to obtain or create information and deliver it to the agency about its competitor's products and formulations. Likewise, a consumer product manufacturer cannot be compelled to obtain or create information about a chemical that is not germane to its use in that manufacturer's product – such as total volumes of such a chemical used statewide. Nor can a consumer product manufacturer accurately or effectively estimate costs to government agencies, e.g., waste removal, for its products or a competitor's products.

Section 69501(b)(3)(A) of the regulations contains another limitation, making clear that the program does not apply to a consumer product that DTSC determines is regulated by one or more federal and/or California State regulatory programs and international treaties that in combination address 1) the same potential adverse impacts, potential exposure pathways, and potential adverse waste and end of life effects that could otherwise be the basis for the listing of a product as a priority product; and 2) that provide a level of public health and environmental protection that is equivalent to or greater than the protection provided if the product were listed as a priority product.[3]

Accordingly, we believe that it would be helpful for the Guide to more clearly note both the purpose and the boundaries of the program. In particular, the Guide should review when consumer product manufacturers are required to "provide additional information needed to assess a chemical of concern and its potential alternatives" and what the scope of such a requirement may be, making clear that while each product manufacturer is responsible for information relevant to the production of its product, it is not responsible for industry-wide information, analyzing costs to government agencies, or generalizing information about its competitors' consumer products.

DTSC should clarify when and how it will make a determination under Section 69501(b)(3)(A) that a consumer product is otherwise regulated and outside the scope of the SCP program. If a product is already regulated by a federal agency or state with respect to human health and safety during product use, for example, this could affect the scope, scale and focus of an AA. For example, because FDA regulates a food contact polymer for safety with respect to the identified chemical of concern, a food contact product made with that polymer would be outside the scope of the SCP program. We suggest that the DTSC address these constraints on its authority by illustrating when and how the determination will be made within the Stage 1 Guide's flow charts.

[3] The decision to undertake an AA with a broad or sweeping scope should not be confused with the limits of the statute, nor does it imply that regulatory responses outside those authorized by 25253(b) may be taken. For example, an AA that seeks to examine air emissions during manufacture of a consumer product does not mean that DTSC bootstraps new authority under the SCP program to prohibit use of the chemical of concern in the consumer product due to the examined air emissions. Air emissions during manufacture are already regulated under separate California and federal statutes.

DTSC should make clear that while a Responsible Entity may choose to conduct or submit an AA that exceeds the boundaries of the statute, DTSC might lack authority to approve such an AA, or might be limited to approving only the conforming parts of the AA. An example might be an AA that includes consideration and weighting of social justice issues outside the criteria established by statute. The practical consequence is that Responsible Entities should ensure that AAs are conducted within the boundaries of the SCP statute. The scope of an AA with respect to statutory authority should be established upfront, as a necessary and implicit pre-step, before moving to Step 1 of a First Stage AA pursuant to Section 69505.5 of the regulations. It is also consistent with the National Academy of Science's admonition of the importance of performing a scoping step in an AA before moving to identification of potential alternatives, noting that "it is important to explicitly articulate and document assumptions and constraints in advance."[4]

IV. The Guide Should Offer Greater Clarity With Respect to When "New" Information May be Requested by DTSC.

As noted above, the statute provides, at Section 25253(b)(2), that the regulations may impose requirements "to provide additional information needed to assess a chemical of concern and its potential alternatives." Section 69501.4(a)(1)(D) of the regulations instruct DTSC that it shall "seek to obtain" new information from product or chemical manufacturers, importers, assemblers, and retailers, but only when DTSC has made a determination that the information is "necessary" to implement the law. The regulation also characterizes how DTSC shall "seek" to obtain this information: by request, not compulsion.[5]

We suggest that DTSC more squarely address the question of how and when it may request "new" information under the Guide. DTSC should acknowledge that the development of new information is significantly more burdensome, expensive, and potentially complex than compiling existing information. The creation of "new" information can come with additional issues: information may be assembled hastily; it may not have been published, peer reviewed, audited, or subject to other scrutiny for quality and reliability. New information about an alternative chemical may be difficult, if not impossible, for a responsible party to obtain. It would be helpful for DTSC to indicate scenarios when the request of such new information would be valuable in the preparation of a Stage 1 AA. Because DTSC can only make requests for new information on a voluntary basis, it would be particularly helpful for DTSC to explain why responsible entities may wish to participate. It would also be helpful for DTSC to explain that if it makes such information requests, it will advise all parties receiving such requests of the identity of all other recipients, and it encourages (for cost sharing, efficiency, and quality purposes) recipients to consider consortia or trade-association based submittals of new information collectively, where legally appropriate. Responsible entities receiving requests for new information should also be invited to identify other entities and third parties who might have relevant information and may be subject to a request for information from DTSC.

[4] National Academy of Sciences, Report in Brief, A Framework to Guide Selection of Chemical Alternatives, October 2014.
[5] As we read the statute and implementing regulations, DTSC does not have and does not claim authority to compel new information. Commentary by DTSC and Green Ribbon Science Panel participants at the November 12-13 meetings likewise seemed to acknowledge that DTSC is limited under the statute to "seeking" additional information and may not compel it. If DTSC believes it does have such authority, however, it needs to articulate this clearly, and needs to offer plain, transparent guidance with respect to when and how such information will likely be requested. Responsible entities need to know up front what they need to do to prepare an acceptable Stage 1 AA; it is inefficient, unfair, and burdensome to ask Responsible Entities to answer ongoing, ad hoc requests for "new" information throughout the AA process.

V. The Guide Should Expressly Allow Function, Performance, and Cost to be Considered Early in the First Stage AA.

The statute itself requires consideration of product function or performance as the first of thirteen discrete listed criteria in life cycle assessment tools. Section 69505(a)(1) of the Regulations directs Responsible Entities to identify functional, performance, and legal requirements of the Priority Product that must be met by alternatives under consideration. And, as a practical matter, it is now clear in the alternative assessment community that product performance and function is a built in precondition to the success of an AA.[6] It is thus important that the Guide clarify that function and performance may be considered in the Stage 1 AA (and indeed, that in some cases these must be considered in Stage 1), and if it is readily apparent that a function or performance trade off will be unacceptable, that the agency will accept this information. We can envision many consumer product scenarios where even the most cursory start to an AA quickly reveals that certain alternatives will be unacceptable from a functional or performance standpoint. This may be particularly true where (1) the performance is essential to a critical safety or security function of the consumer product, such as shatter resistance of safety glasses; (2) more than one product would be needed to achieve the same function, such as multi-functional spray polyurethane foam insulation compared to a flash and batt insulation system; or (3) where it is apparent that performance or function will be substantially diminished by moving to an alternative. In such cases, the process benefits greatly from early recognition and acknowledgement that no suitable alternatives are currently available, enabling the agency to move more quickly to pursuing options such as access controls, exposure limitations, or green chemistry grants.

VI. The Guide Should Provide Greater Clarity with Respect to Responsible Entities' Use of the Designated "Off Ramps" from the AA Requirements.

The regulations allow a product manufacturer to avoid the AA requirements by ceasing to offer the Priority Product in California containing the chemical of concern. While the regulations make it relatively easy for manufacturers of Priority Products to submit notifications of intent, they invite new questions about what documentation the agency will require to demonstrate compliance. The Removal/Replacement provision also discourages conduct of industry-wide AAs; it makes it relatively easy for a single manufacturer to escape calls to contribute to a joint-industry funded AA by simply submitting a removal/replacement notification. The manufacturer could then delay submitting its confirmations, or change its notification based on the results of the industry-wide AA. Given that industry-wide AAs may be better resourced and funded, more comprehensive in scope and complete, and internally consistent (as opposed to multiple AAs conducted with different methodologies, which are more likely to yield conflicting results), DTSC should offer additional guidance to ensure that compliance requirements are well understood by those seeking to exercise the Removal/Replacement option. Likewise, the agency should explain how it will follow up to verify compliance over time, and enforce against non-compliance.

Another regulatory AA "off ramp" is notification to DTSC that the presence of the chemical of concern is below the Alternatives Analysis Threshold (AAT). The design of the regulations is that the Responsible Entity may avoid the need to perform an AA at all by certifying to DTSC either that the chemical of concern is in the Priority Product at a concentration at or below the Practical Quantitation Limit (PQL), or, that it is at or below an Alternatives Analysis Threshold to be specified by DTSC. Guidance is needed on several points. First, it would be helpful for the agency to explain whether it plans to set the PQL for a chemical in a Priority Product or whether it will accept a PQL identified by a Responsible Entity as

[6] See, e.g., NAS, A Framework to Guide Selection of Chemical Alternatives at (2014), "It is understood that the safer alternatives would also meet other requirements, such as cost and performance." (emphasis added).

"applicable." In either case, it would be helpful if the agency could provide additional guidance on how a PQL is to be selected or established. PQL procedures set by other agencies and other states often use the same or similar definition of PQLs, but may also require the use of agency approved methods for lab testing.[7]

The agency itself will designate what the AAT is to be for a chemical in a priority product. The regulations suggest that the AAT either be the same as the PQL or higher. That said, the regulations do not offer any insight as to how or when the agency might establish an AAT. A well-articulated AAT process will make it easier for Regulated Entities to anticipate what the AAT is likely to be earlier in the process, which may help avoid the need to undertake costly AA preparations.

Certain scenarios may lend themselves well to AATs, particularly given the agency's obligation to have made a threshold determination whether the presence of a chemical of concern in a Priority Product is already regulated by a state or federal authority. It may be the case, for example, that a safety level has already been established for the chemical in another product or application where exposures can or are calculated to be higher than from the Priority Product. An example is a direct or indirect food additive regulated by the FDA. If FDA establishes a safe level of a particular chemical as a food additive, the FDA level may be suitable as the AAT in a Priority Product where exposure would be projected to be significantly lower than the level deemed safe for food. It could be helpful for DTSC to establish a default procedure for adoption of AATs, using, for example, FDA-established food additive levels as the AAT for Priority Products.

We also note that the AATs may have additional utility in the AA itself, and guidance on this point could be helpful. To the extent that DTSC does establish an AAT and the chemical of concern is present in the Priority Product above the AAT, does the agency intend the AAT to have any meaning or utility in the AA itself?

VII. The Guide Should Seek to Have Alternative Analyses Conducted In a Consistent Manner for Integrity and Reliability.

The complexity of the DTSC's Alternatives Analysis requirements is staggering, with its multiple factors, associated exposure pathways and life cycle segments. Both Section 69505.5 of the Regulations and the Stage 1 guide qualify the required elements of the AA by noting that only those that are "relevant" for the comparison of the priority product and the alternatives need be considered. But in other parts of both the regulations and the guidance, it is less clear that only "relevant" factors need to be addressed in the AA. The Guide offers no assistance to Responsible Entities as to how they are to determine which factors are relevant, although its places a burden, nonetheless, on Responsible Entities to explain in the AA report the basis for each conclusion that every factor, exposure pathway and life cycle segment that is excluded is not relevant.

It is highly desirable that AAs take a reasonably consistent approach from Priority Product to Priority Product. It is clearly counterproductive to have multiple Responsible Entities conduct multiple AAs and achieve different results. DTSC might also offer additional guidance as to the process it would use to reconcile, if possible, conflicting and inconsistent AAs.

We urge DTSC to better explain its expectations for the conduct of the AAs. There are several avenues to accomplishing this. DTSC could, for example, add more detailed decision trees to the Stage 1 Guide (and

[7] See, e.g., Washington Department of Ecology, WAC 173-340-200, defining a PQL as "… the lowest concentration that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness, and comparability during routine laboratory operating conditions, using department approved methods." (emphasis added).

the Stage 2 guide as well); consider ways in which the AA requirements could be streamlined and simplified; consider suggesting "weightings" for the factors that must be included in the AAs (e.g., using upfront identification of decision methodologies); include multiple examples of AAs that would be likely to obtain DTSC approval; conduct training for both DTSC reviewing staff and Responsible Entities on how to develop a consistent AA; and conduct workshops with the Responsible Entities, especially those for the first set of priority products.

VIII. The DTSC's Criteria for Review and Determinations for AA Reports and Work Plans (and the underlying AAs) Need to be Clarified.

The Stage 1 Guide should better describe how the DTSC will make compliance determinations about the submitted AAs. The regulations at Section 69505.9 provide only 3 relatively superficial criteria by which the DTSC will judge compliance with the requirements: (1) whether the report was timely submitted; (2) whether and to what extent the Responsible Entity considered and addressed all applicable provisions pertaining to the preparation and submittal of an AA report; and (3) whether and to what extent the Responsible Entity demonstrated that the conclusions of the AA were based on "reliable" information. DTSC could provide useful guidance by describing what information it will consider "reliable." Likewise, it would be helpful to offer commentary on how DTSC will judge whether the AA touched on all the relevant factors.

Responsible Entities ultimately will find the Guide to be most useful to the extent that it helps them prepare AAs that will be accepted by DTSC. While we appreciate that the regulations set out DTSC's legal requirements, it would be helpful to have additional guidance as to DTSC's decision criteria for AAs and key components thereof – and anticipated timelines for DTSC's action on submissions.

IX. The Guide Should Include More Suggestions on How Responsible Entities Can Comply with AA Requirements in a Cost Effective Manner.

To conduct an AA, the Guide lists the need for expertise in chemistry, toxicology, environmental fate and transport, environmental and occupational health and safety, process engineering, life cycle thinking, project life cycle management, environmental economics, financial analysis, public health, green chemistry, and marketing. Yet the Guide includes no discussion about how Responsible Entities can obtain this expertise in a cost effective manner within the aggressive timelines included in the regulations. We suggest that the Stage 1 Guide include a discrete section on how Responsible Entities can meet the Alternatives Analysis requirements as cost effectively as possible. In particular, DTSC should encourage Responsible Entities to seek the use of consortia, often organized through trade associations, as a more efficient and cost effective mechanism to share costs.

X. Exposure Factors Need Greater Attention in the Guide.

The field of alternatives assessment has seen significant advancement since the passage of the original package of "green chemistry" legislation in 2007. The underpinnings of the legislation are now outdated and frankly misaligned with the state of the art of alternatives assessment. DTSC should take note of evolving thinking on the incorporation of quantitative exposure assessment information in alternatives assessment, as evidenced in the National Research Council's 2014 "Framework to Guide Selection of Chemical Alternatives" and the ILSI Health and Environmental Science Institute's new project on incorporation of exposure information in alternatives assessment.

Specific Comments

- **Explanation of Program Differences and Nomenclature:** At the Green Ribbon Science Panel meeting on November 12, a presentation was made noting unique aspects of California's Safer Consumer Products program compared to other chemical alternatives programs. These features were noted to include consideration of a specific list of relevant factors, required consideration of full life cycle impacts, the ability of a Responsible Entity to consider alternatives other than chemical substitution (e.g., material, product, or system substitution), and the lack of a mandatory requirement for Responsible Entities to generate new data. During the Panel discussion, comments were made that it would be helpful for the Guide to include this discussion of the features unique to the SCP program. We agree. As part of that discussion, we also encourage DTSC to provide further clarification with respect to the SCP's modification of terms that are commonly known or have standardized meaning to the regulated community. A glossary may be an effective way to achieve this. Here are some examples of terms that could be better explained and defined:

    - "Alternatives assessment" versus "alternatives analysis": On page 9, footnote 1 asserts there is a difference between "alternatives analysis" and the "alternative analyses" required by the SCP regulations. The footnote implies that DTSC's alternatives analyses are more comprehensive than any of the frameworks for alternatives assessments. We suggest that DTSC carefully explain in the Guide how a SCP "alternatives assessment" deviates from an "alternatives assessment" as that term has now come to be known in light of Alternative Assessment frameworks such as the NAS National Research Council's "Framework to Guide Selection of Chemical Alternatives" (which includes 13 steps including conduct of comparative exposure assessments). We also suggest that DTSC re-visit this footnote in the Guide to ensure that it is up to date; DTSC should also take note of ongoing discussions within HESI about the incorporation of exposure assessment in alternatives assessment. The Guide's footnote 1, in essence, does not reflect the evolving nature of alternatives assessment. The DTSC should revise this footnote accordingly.

    - Use of life cycle terms: existing voluntary consensus standards already define a number of terms, such as "Multi-Attribute Decision Analysis" under ASTM E1765, "Life-Cycle Costing" under ASTM E917, and of course "Life Cycle Assessment" under ISO 14040. To the extent that DTSC intends an activity to have the same meaning under the SCP as defined in voluntary consensus standards, it should simply reference and adopt the standard without modification. To the extent that DTSC intends to deviate from a standard, it should articulate this intention and clearly explain the difference in the Guide.

- **Examples of Tools for Comparing Hazards:** Table 4-4 offers a number of examples of tools for comparing hazards, including GreenScreen, Cradle to Cradle, and Safer Choice. None of these tools, however, incorporate exposure; this limitation should be expressly noted. To the extent that DTSC offers lists of "examples" of tools for comparing hazards, it may wish to provide objective commentary regarding key features and limitations of the tools beyond the descriptions presented in Appendix 4. (We note that the commentary in the Draft Guide seems to come rather close to "recommending" use of GreenScreen, or at least suggesting DTSC's imprimatur of the tool). Safer Choice is a partnership program of EPA and its criteria are not suitable for use outside the context of that program. This limitation should be expressly noted in the commentary. We also suggest that SciVera Lens, PDTEC (3E), and GreenSuite be added with commentary.

The AA field is advancing rapidly, and new tools blending hazard and exposure are becoming available. DTSC may wish to encourage Responsible Entities to use state of the art tools as opposed to inherently limited first generation, hazard-only tools. Because the field is developing so rapidly, it would be helpful to maintain lists and examples on an evergreen basis.

- **Establishment of AA Team:** the box at page 15 notes a series of fields of expertise that could be helpful to conducting an AA. Given the importance of exposure factors and exposure pathways in the AA process, it would be helpful to include exposure assessment and risk assessment in the fields of expertise.

- **Material Difference and Material Contribution:** On pages 16 and 33, in step 3 DTSC discusses "material difference and material contribution" in its discussions of what are "relevant factors" for AAs. The explanation of these terms on page 33 are vague. DTSC should provide examples to better clarify how a responsible entity might make these judgments in the AA and whether/how these terms create a yardstick for compliance or acceptability of the information submitted.

- **Confidential Business Information:** The Guide should clarify how CBI will be addressed throughout the Stage 1 process.

- **Research and Development:** The Guide's discussion of "Abridged AAs" (pp 19-20) makes clear that if a suitable alternative cannot be identified, DTSC will issue a "regulatory response" determination for the Priority Product which, at a minimum will require the Responsible Entity to provide product information to consumers and conduct an R&D project or fund a challenge grant. DTSC must provide more details in the Guide about these requirements and DTSC's expectations. Guidance on the following points would be helpful:

    - How must a manufacturer conduct R&D? The goals of the R&D include product improvement, reduction in costs, etc. How are the goals for the R&D established, and the costs estimated?
    - If R&D is required, can it be done in-house, by a consortium, or by a third party?
    - How much time would be allowed to complete the R&D?
    - May the R&D be proprietary to the funders?
    - Who owns the patent rights to any discovery made in the course of the R&D?
    - If patent applications have already been filed by others, what are the DTSC's expectations/requirements with respect to the manufacturer of the priority product?
    - Will DTSC require all Priority Product manufacturers share in the costs of the work?
    - Would R&D include consideration of the economic feasibility of commercially manufacturing the product?
    - Would R&D include market research on consumer acceptability?
    - How does a Responsible Entity address consumer resistance to an alternative identified through R&D?

DTSC regulations are silent on these thorny issues; DTSC guidance should provide greater clarity.

- **Abridged Alternatives Analyses:** In the discussion of "Abridged AAs" on pp 19-20, DTSC makes clear that most of the elements of the standard AAs are required of the abridged AAs. However, for abridged AAs to have value, they should present a meaningful path to a shorter, condensed report. For that matter, if alternatives are identified that meet the function and

performance requirements of the Priority Product, but are not feasible as the outcome of the Abridged AA, then imposing an R&D requirement is excessive and potentially open-ended. We suggest that additional discussion be offered so the role and availability of an abridged AA is clear, and in particular, when a requirement for additional R&D may not be needed.

- **Exemption for Removal of Chemicals not Needed for Product Function:** Page 29-30 of the Stage 1 Guide briefly discusses this exemption, but does not provide sufficient detail. DTSC should include more information in the guide on this and include some of that detail in the discussion of "initial steps" in Figure 1-2 on page 18 and elsewhere in the guide. Again, a more detailed "decision tree" for the entire Stage 1 process would help Responsible Entities better understand DTSC's expectations and the AA regulations.

- **List of Factors and Endpoints in Appendix 3-1**: This list of factors and endpoints reveals the complexity of the California AA process. In our view, merely listing all the potential health/environmental endpoints is not helpful guidance. We suggest that a more helpful approach for the regulated community would be for DTSC to develop a decision tree applying the AA factors. Long experience teaches that for toxicity endpoints in particular, tiered testing approaches are more rational, cost effective, and less animal resource intensive; DTSC should seek to offer tiered approaches here.

- **Exposure Pathways:** One of the relevant exposure pathways discusses potential ecological receptors that could be exposed to potential releases. We are concerned that without clear guidance, it is unclear how a Responsible Entity is to gather this information from actual and potential raw material suppliers within the short timelines described in the AA process and regulations. In addition, the Guide allows the use of "conceptual models" to depict interactions with exposure pathways. However, conceptual models have severe limitations for such a use; they are generally considered a mere starting point to identifying exposure pathways. The exposure pathways section of the AA process lacks rigor and is inconsistent with the current state of the art for exposure assessment.

- **Economic Considerations:** Economic considerations should be addressed in Stage 1 of the analysis, and not deferred to Stage 2. The Guide should be clear that economic considerations may be considered.

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We appreciate the opportunity to comment.

Respectfully submitted,

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